PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference NSM4831PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/JP2005/004953	International filing date *(day/month/year)* 18 March 2005 (18.03.2005)	Priority date *(day/month/year)* 18 March 2004 (18.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant NISSUI PHARMACEUTICAL CO., LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

   - [x] Box No. I — Basis of the report
   - [ ] Box No. II — Priority
   - [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV — Lack of unity of invention
   - [x] Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI — Certain documents cited
   - [ ] Box No. VII — Certain defects in the international application
   - [ ] Box No. VIII — Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 18 October 2006 (18.10.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Masashi Honda e-mail: pt08@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	10 MAY 2005
Applicant's or agent's file reference NSM4831PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/004953	18.03.2005	18.03.2004

International Patent Classification (IPC) or both national classification and IPC
G01N 33/53, G01N 37/00

Applicant
NISSUI PHARMACEUTICAL CO., LTD.

1. This opinion contains indications relating to the following items:

- [x] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [x] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP Facsimile No.	Authorized officer Telephone No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/004953

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☒ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☒ in computer readable form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.

      ☒ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/004953

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-57	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-57	NO
Industrial applicability (IA)	Claims	1-57	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP 2003-156493 A (Multilyte Ltd.), 30 May 2003; claims and paragraphs [0026] and [0027] & WO 1995/024649 A1 & EP 0749581 A & US 2002/0182617 A1

Document 2: JP 2003-522963 A (Aclara Biosciences Inc.), 29 July 2003; claims and paragraphs [0008], [0039] and [0040] & WO 2001/061041 A2 & US 2002/0058329 A1 & EP 1259324 A

Claims 1-57

Document 1 cited in the international search report discloses a method for measuring the concentration of a test substance whereby a plurality of antibodies, which are ligands which bind specifically with the test substance, are immobilized via a plurality of different nucleic acids in separated positions on a solid support (see claims). It also discloses the adoption of a competitive or non-competitive immunoassay method as the method for detecting the test substance (see paragraph [0026]), and enzymes, chemiluminescent substances and fluorescent substances as labels (see paragraph [0027]).

Document 2 cited in the international search report

discloses a method for detecting amino acids by using a microchip having a flow path wherein a nucleic acid having a sequence complementary to that of the nucleic acid to be detected is immobilized in a reaction region (see claims).

Documents 1 and 2 are inventions relating to methods and devices using assays in order to detect biological target substances; therefore, a person skilled in the art could easily conceive of using a reaction device with a plurality of sites having flow paths disclosed in document 2 for small-volume reactions as the stationary phase of a detection method for detecting a plurality of test substances disclosed in document 1, with antibodies immobilized via nucleic acids.

Moreover, construction of an analytical device using such a method of analysis, production a kit which includes the reagents employed among the constituent elements, and modification of the constitution of the kit such as including the necessary reagents in the same system or separately, are within the scope of ordinary creative skill for a person skilled in the art.

It should be noted that the width and depth of an analytical device are matters of design which can be decided at the discretion of the person skilled in the art; and the width and depth for the groove specified in document 2 are 20-1000 μm, which are sizes included within the ranges in the present application.

Methods using a third ligand which binds specifically to the second ligand are commonly known in

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

the immunoassay field as methods for detecting test substances.

The materials for the first member and second member are also such as can be selected at the discretion of a person skilled in the art. And document 2 discloses polypropylene, glass, polyethylene, polycarbonate and dimethylsiloxane (see paragraph [0039]).

The flow rate in the flowpath can also be set at the discretion of a person skilled in the art. Moreover, no special effect is offered by making the flow rate 0.1-50 μL/minute.

As also disclosed in document 2, construction of an analytical device from a member having a groove and a member which can cover the groove is known (see paragraph [0040]). From documents 1 and 2, a person skilled in the art could easily conceive of a method for producing an analytical device wherein, instead of the captive nucleic acid in the analytical device disclosed in document 2, a nucleic acid is immobilized as a capturing agent disclosed in document 1, followed by connection of a second member, and immobilization of a binding member having a sequence complementary to the capturing agent and a ligand which binds specifically to the substance to be tested